

### **REMARKS**

Applicants thank the Examiner for taking time to discuss the outstanding Office Action with Applicants' undersigned representative on October 14, 2005. In accordance with that discussion, and in view of the present amendment and remarks, reconsideration of the rejections set forth in the Office Action dated August 9, 2005, is respectfully requested.

Applicants have canceled claims 1, 6 and 12, and have amended claims 5, 9, 10, 11, and 13. Applicants have also added new claim 14. All of the amendments and new claims are supported in the original specification, and no new matter has been added by way of these amendments. Claims 5, 9, 10, 11, and 13-14 are now pending in this application.

#### **Rejection of Claims 1 and 5 under 35 U.S.C. §103(a)**

The Examiner rejected claims 1 and 5 under 35 U.S.C. §103(a) for allegedly being unpatentable over Alferness, in view of Laufer *et al.* (6,083,255). Applicants have canceled claim 1. Claim 5 has been amended to overcome the Examiner's rejection.

In order to establish a *prima facie* case of obviousness, there must be evidence, preferably a teaching, suggestion, incentive or inference from the cited art or in the form of generally available knowledge that one of ordinary skill in the art would have been led to modify the relevant teaching to arrive at what is claimed. The prior art must provide a motivation whereby one of ordinary skill in the art would have been led to do that which the applicant has done. In addition, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.

#### **Claim 5**

Claim 5 recites a system for obstructing a lung passageway to a lung tissue segment, said system comprising:

an access catheter having a proximal end, a distal end, and at least one lumen extending therethrough, and

a valve deployable within the lung passageway having an inlet port adapted for suctioning the lung tissue segment through the inlet port,

wherein the valve is introducible by the access catheter.

Neither Alferness nor Laufer, nor the combination of the two, teaches or suggests a valve having an inlet port adapted for suctioning the lung tissue segment through the inlet port. Laufer does not teach valves at all, and is irrelevant to the content of the claims as amended herein. Meanwhile, Alferness actually teaches away from suctioning through the inlet port of a valve deployed within the lung passageway (see col. 5, lines 60-64), because it teaches other ways of deflating a diseased lung segment. Alferness teaches suctioning a lung section and subsequently implanting an obstructing member to prevent air from entering that lung section (see col. 5, lines 11-46). Alternatively, Alferness describes placing an obstructing member without suctioning the lung section at all (see col. 5, lines 54-64). In yet another alternative, Alferness shows a one-way valve that can be placed in a lung passageway to permit exhaled air out of the lung while preventing air to be inhaled into the lung portion beyond the location of the one-way valve. As described at col. 5, lines 54-64 and also at col. 6, lines 56-65, Alferness teaches that in this alternative embodiment the obstructive member is placed in the air passageway and no vacuum is pulled to aspirate and collapse the lung tissue segment. None of these methods of collapsing a lung segment involves suctioning through a valve. Thus, there is no motivation or suggestions for suctioning through the valve given that suctioning the lung segment is accomplished in other ways.

Thus, the combination of Alferness and Laufer neither teaches nor suggests a valve deployable within the lung passageway having an inlet port adapted for suction through the inlet port. Accordingly, applicants respectfully submit that claim 5 is

patentably distinct from Alferness and Laufer and request that the Examiner withdraw the rejection of claim 5.

**Rejection of Claims 6 and 13 under 35 U.S.C. §103(a)**

The Examiner rejected claims 6 and 13 under 35 U.S.C. §103(a) for allegedly being unpatentable over Alferness, in view of Laufer *et al.* (6,083,255) and in further view of Daniel *et al.* (5,980, 455). Applicants have canceled claim 6. Claim 13 has been amended herein to overcome the Examiner's rejection.

As described above, claim 13 includes the limitation of "...suctioning the segment through the deployed valve to at least partially collapse the lung segment". Neither Alferness, Laufer nor Daniel disclose this limitation nor do they teach or suggest the desirability of suctioning a lung segment through a deployed valve. As explained above, Alferness actually teaches away from such a limitation. Accordingly, applicants respectfully submit that claim 13 is patentably distinct from the prior art cited by the Examiner.

**Rejection of Claims 9, 10 and 12 under 35 U.S.C. §102(e)**

The Examiner rejected claims 9, 10 and 12 under 35 U.S.C. §102(e) for allegedly being anticipated by Alferness *et al.* (US 6,293,951). Applicants have canceled claim 12. Claims 9 and 10 have been amended to overcome the Examiner's rejection.

Anticipation under 35 U.S.C. §102(e) requires the disclosure in a single reference each element of the claim under consideration. All limitations of the claim must be found in the reference. Moreover, it is incumbent on the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference.

Applicants respectfully submit that Alferness fails to anticipate claim 9 for at least the following reasons. Alferness does not teach at least two steps recited in claim 9. Alferness fails to teach the step of passing a suction catheter through the valve so that the suction catheter is in fluid communication with the lung tissue segment. Alferness

also fails to teach the step of suctioning the segment with the suction catheter through the deployed valve to at least partially collapse the lung segment. Accordingly, claim 9 is patentably distinct from Alferness.

Applicants respectfully submit that Alferness fails to anticipate claim 10 for at least the following reason. As described in more detail above, Alferness does not teach the step of suctioning the segment through the deployed valve to at least partially collapse the lung segment. Rather, Alferness discloses aspirating the lung through a balloon member 74 *prior to* inserting the valve 90 in the lung. Thus, aspiration does not occur through the valve 90 in Alferness. Because Alferness fails to disclose each and every element of claim 10, applicants respectfully submit that claim 10 is patentably distinct from Alferness.

#### **Rejection of Claim 11 under 35 U.S.C. §103(a)**

The Examiner rejected claim 11 under 35 U.S.C. §103(a) for allegedly being unpatentable over Alferness, in view of Laufer *et al.* (6,083,255). Applicants have amended claim 11 and respectfully traverse this rejection.

Claim 11 is dependent upon claims 9 or 10 and further comprises the step of delivering the valve to the lung tissue segment through an internal lumen of an access catheter. As described above, both claims 9 and 10 are patentably distinct from the prior art and include limitations that are not described in any of the references cited thus far. Accordingly, claim 11 is patentably distinct from the prior art based on its dependency on claims 9 or 10, as well as on its own merit. Applicants request that the Examiner withdraw the rejection of claim 11.

#### **Claim Objections**

Claim 12 is objected to because of the omission of the word "device." The cancellation herein of claim 12 renders this objection moot.

Applicant : Mark E. Deem, et al.  
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Response and amendment


## **Conclusion**

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to it amendment.

Applicants respectfully submit that the pending claims are now in condition for allowance and respectfully request the same. If the Examiner has any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,

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Mikael Havluciyani  
Reg. No. 47,285

**PTO Customer No.: 20985**  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-5613  
Facsimile: (202) 626-7796  
Email: havluciyani@fr.com